K032280

SEP 1 0 2003

510(K) SUMMARY
FOR THE
SIREMOBIL ISO-C 3D

Submitted by:

Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

July 18, 2003

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Nealie Hartman
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787

2. Device Name and Classification:

Trade Name:	Siremobil Iso-C 3D
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	90IZL

3. Substantial Equivalence:

The Siremobil Iso-C 3D is designed for three-dimensional evaluation of data acquired with an isocentric mobile C-arm device. The package is substantially equivalent to the following devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Siremobil Iso-C 3D	K003266	12/01/00
GE OEC Flexi View 8800	K003837	03/12/01
Philips BV Endura	K010435	03/12/01

4. Device Description:

The Siremobil Iso-C 3D is an isocentric mobile x-ray C-ram which consists of a high frequency generator, X-ray tube assembly, image intensifier, TV camera, film cassette attachment, Laser light localizers, electronics cabinet and a monitor trolley which consists of the digital memory device, image monitor(s), and user interface. The 3D Imaging option allows the reconstruction of two-dimensional images

acquired with a mobile isocentric C-arm device into a three-dimensional image format.

5. **Intended Use of the Device:**
The Siremobil Iso-C 3D is intended to be used whenever the surgeon benefits from intraoperatively generated 3D information of high contrast objects (bones and joints). The Siremobil Iso-C 3D focuses on complex bone or joint fractures of the upper and lower extremities (including knee, foot, elbow, hand), and the entire spine.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The Siemens Siremobil Iso-C 3D with extended Indications for Use and the predicate devices allow reconstruction of a three-dimensional model from a series of two dimensional images acquired with a C-arm imaging device.

Nealie K. Hartman

Nealie Hartman
Technical Specialist, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Siemens AG
% Ms. Nealie Hartman
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K032280
Trade/Device Name: Siremobil Iso-C 3D
Mobil X-Ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: July 18, 2003
Received: July 25, 2003

Dear Ms. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHEMENT 2

INDICATIONS FOR USE

510(k) Number (if known):_____
Device Name: **Siremobil Iso-C 3D**

Indications For Use:

The Siremobil Iso-C 3D with extended Indications for Use is based on Siemens isocentric mobile C-arm, marketed as Siremobil Iso-C 3D. The extended Indications for Use to include the entire spine for the Siremobil Iso-C 3D contains no new hardware or software

The Siremobil Iso-C 3D is intended to be used whenever the surgeon benefits from intraoperatively generated 3D information of high contrast objects and anatomical structures (e.g. bones and joints). The Siremobil Iso-C 3D is designed as a 3D imaging device for conditions such as complex bone or joint fractures of the upper and lower extremities (including knee, foot, elbow, hand), and the entire spine.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032280

Prescription Use _____ OR ~~Over-The-Counter Use~~_____
(Per 21 CFR 801.109)